THE CENTERS FOR MEDICARE & MEDICAID SERVICES

Open Door Forum Newsletter

February 2003

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Stats of the Month!

1,309 teleconference lines were open to individual and group participants and more than **166** guests visited with the CMS Administrator and policy leaders during the 12 Open Door Forums held in the month of January.

To date, more than **14,400** guests have participated in the forums since October 2001.

Hot Announcements!

2003 Medicare Physician Fee Schedule

President George W. Bush recently signed legislation to correct the physician fee schedule error for 2003. The new law includes a **1.6 percent positive** increase in physician payments for 2003 – rather than the negative 4.4 percent cut in payment that would have occurred had President Bush not signed the law.

CMS has moved quickly to implement the new physician fee schedule rates; the regulation is on display (click here to view a copy: http://cms.gov/regulations/pfs/cms1204f2.pdf) and, as of February 28th, will be published in the *Federal Register*. All physicians and practitioners now have until April 14th, to make their 2003 Medicare participation decision. For additional details and to view the Q&A Document, please click here: www.cms.hhs.gov/physicians/pfs//. Implementing instructions will be posted to the CMS website when the final rule is published.

Also contained in this legislation is the elimination of the rural standardized amount. This is good news for America's rural hospitals. CMS will issue an instruction soon implementing this provision of the law.

Hooray!!!

HIPAA Security Standards and Modifications to HIPAA Transactions and Code Set Standards Rules Published

As part of the administrative simplification provisions included in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), HHS Secretary Tommy G. Thompson recently announced the adoption of final security standards for protecting individually identifiable health information when it is maintained or transmitted electronically. At the same time, he also announced the adoption of modifications to a number of the electronic transactions and code sets adopted as national standards.

"Overall, these national standards required under HIPAA will make it easier and less costly for the health care industry to process health claims and handle other transactions while assuring patients that their information will remain secure and confidential," Secretary Thompson said.

**Continued on page two



Information Disclaimer: The information provided in this newsletter is only intended to be general summary information to the public. It is not intended to take the place of either the written law or regulations.

Links to Other Resources: Our newsletter may link to other federal agencies and private organizations. You are subject to those sites' privacy policies. Reference in this newsletter to any specific commercial products, process, service, manufacturer, or company does not constitute its endorsement or recommendation by the U.S. Government, HHS or CMS. HHS or CMS is not responsible for the contents of any "off-site" resource referenced.



The security standards are designed to help safeguard confidential health information as the industry increasingly relies on computers for processing health care transactions and specifies a series of administrative, technical, and physical security procedures for covered entities. The standards are delineated into either required or addressable implementation specifications. The rule adopting changes to the electronic transactions and code set standards modifies a number of the electronic transactions and code sets and eliminates the National Drug Codes (NDC) code set as the standard for all providers except retail pharmacies. It does not adopt a standard reporting drugs and biologics on non-retail pharmacy transactions.

CMS is responsible for implementing and enforcing the security standards, the transactions standards and other HIPAA administrative simplification provisions, except for the privacy standards. HHS' Office for Civil Rights is responsible for implementing and enforcing the privacy rule.

The complete text of both final rules will be available at the CMS website at: www.cms.hhs.gov/hipaa/hipaa2. The full text of the Addenda to the transaction modifications rule will be available at http://hipaa.wpc-edi.com/HIPAAAddenda_40.asp

7th HIPAA Roundtable Conference Call

CMS' Office of HIPAA Standards (OHS) and our Regional Office counterparts are working hard to educate covered entities and others about compliance with key upcoming deadlines for HIPAA Administrative Simplification. By law, covered entities that filed before October 16th, 2002 for a one-year extension to comply with the HIPAA electronic transactions and code sets requirements, now have until October 16th to comply.

Congress, however, requires that these entities begin testing their systems no later than April 16th in preparation for meeting the October deadline. To help ensure that CMS can better assist those who need to meet this requirement within two months, we are proud to host its 7th HIPAA Roundtable Conference Call on February 28th at 2:00 PM ET.

The call in number for this free event is (877) 381-6315 and the conference identification number is 8096358. If, for some reason, you cannot participate on the live call, a 72 hour reply will be made available starting Monday and ending Wednesday at midnight; you can access the replay by dialing (800) 642-1687 and using that same conference identification number.

Please stay tuned to the updated website for more information on free events, free products, and new rules by going to www.cms.hhs.gov/hipaa/hipaa2/default.asp

PLEASE SPREAD THE WORD TO ALL YOUR MEMBERS, HEALTH CARE PROVIDERS, AND HIPAA EMAIL LINKS & LISTS!

Provider Bad Debt Payment

Please click here: http://frwebgate3.access.gpo.gov/cgi-bin/waisgate.cgi?
WAISdocID=35484614361+0+0+0&WAISaction=retrieve for the full Provider Bad Debt Payment
Proposed Rule, which would remove the cap on allowable Medicare bad debt for end-stage renal
disease (ESRD) facilities and expand the application of a 30 percent reduction in bad debt
reimbursement for hospitals to other Medicare providers or entities currently eligible to receive
bad debt reimbursement. In addition, this proposed rule would clarify that bad debts are not

allowable for entities paid under reasonable-charge or fee schedule methodologies. The goal of this proposal, with respect to bad debt payment, is to achieve a consistent bad debt reimbursement policy for hospitals and other providers or entities currently eligible to receive payments from Medicare for bad debt.

CMS strongly encourages those interested in submitting comments for consideration to do so if we received at the appropriate CMS address, as provided in the link above, no later than 5 PM ET on April 11th.

President Proposes \$1.75 Billion to Help Americans with Disabilities

President Bush has proposed a new \$1.75 billion, five-year program to help Americans with disabilities transition from nursing homes or other institutions to living in the community.

The proposal is one of several new efforts to be included in the FY 2004 budget for the President's New Freedom Initiative, a nationwide effort to integrate people with disabilities more fully into society. Altogether, the President's New Freedom budget proposals will represent \$2.1 billion in planned new spending over five years, with \$417 million in new spending proposed for FY 2004.

The proposals build on recommendations made to the President last year in "Delivering on the Promise," a comprehensive survey of federal policies and rules that may impede community living for those with disabilities.



"The President and I are committed to changing policies that unnecessarily confine people with disabilities in institutional settings. We want to work with the states and the disability community to change old programs and develop new ones that will serve people with disabilities in the settings that work best for them," said HHS Secretary Tommy G. Thompson.

To review demonstration and funding specifics with regard to this great news, please click here: www.hhs.gov/news/press/2003pres/20030123.html

Where We Are: New Freedom Initiative

Two years ago this week, President Bush launched the New Freedom Initiative, one of his first major acts in office. This initiative, aimed at eliminating the many barriers that unnecessarily hinder Americans with disabilities as they seek to participate fully in the life of their communities, has been met with significant vigor on the part of HHS. In the past two years, we have delivered to the President a thorough inventory of federal rules and policies that impact those with disabilities, which included more than 400 recommendations for change.

HHS also created an Office of Disability in the HHS Secretary's office to coordinate activities throughout HHS that impact on those with disabilities. Through our Office for Civil Rights, we are working to help bring about fulfillment of the Supreme Court's *Olmstead* decision in a productive and responsible manner. At CMS, we have announced the establishment of a series of special Open Door Forums focused specifically on the New Freedom Initiative; the first forum is scheduled for March 31st at 2 PM EST. While the forum will be held in Washington, DC at the Hubert H. Humphrey Building, participants may also dial **(800)** 837-1935 and use 8656013 as their access number.

As you can see, we are committed toward seeing to fruition the President's goal to increase opportunity and to embrace the abilities and talents of all Americans in every way we can to include significant efforts to support states in their efforts to change their programs that offer needed assistance in the home and community for people with disabilities.

We are proud to announce that we have already provided funds to states for planning this shift and the President's budget for fiscal year 2004 proposes dramatic new programs to support this effort, totaling \$2.1 billion over five years.

For more details on the efforts at HHS, click here: www.os.dhhs.gov/newfreedom and for CMS specifically, click here: www.cms.gov/newfreedom/



Implementation of the Financial Limitation for Outpatient Rehabilitation Services

CMS recently released Transmittal AB-03-018 (www.cms.gov/manuals/pm_trans/AB03018.pdf), which describes how Medicare will implement the financial limits on therapy services in 2003. It includes time frames, amounts, settings and providers who are affected and details the responsibilities of contractors, providers, and beneficiaries.

CMS was requested, as part of the Benefits Improvement and Protection Act of 2000 (BIPA), to study the impact of the absence of therapy caps on therapy utilization under Medicare. These studies are now complete and were recently posted here: www.cms.hhs.gov/medlearn/therapy/ under "Research Tools for Specific Therapy Topics."

The studies are titled as follows:

Urban Institute Report

- -Background and Policy Issues September 2000
- -Impact (Utilization) September 2001
- -PTA Supervision, August 2002

DynCorp

-Outpatient Therapy Utilization September 2002

Home Health Quality Initiative

HHS Secretary Tommy G. Thompson recently announced the next expansion area of the HHS' Quality Improvement Initiative - Home Health Care. The initiative will help people who rely on Medicare and Medicaid programs and their family members find the best home health agency for their needs. In continued efforts to encourage the best of care for our nation's home health beneficiaries, CMS will host a Special Home Health Quality Initiative Open Door Forum on March 27th from 2 to 4:00 PM EST at the Hubert H. Humphrey Building in Washington, DC. For those who wish to participate via teleconference, please dial (800) 837-1935 and use 8437763 as your access number.

In related news, and in reference to the Nursing Home Quality Initiative (NHQI) launched in all 50 states, the NHQI web site has a brand new look designed to be more user friendly; to view, please click here: http://cms.hhs.gov/providers/nursinghomes/nhi/

REMINDER! Expiration of the Rural Add On for Home Health

Under current law the home health 10 percent rural add-on applies to episodes ending on or after April 1, 2001 and before April 1st. This additional 10 percent is provided to the prospective payment system (PPS) rates for home health furnished in a rural area where the site of service of the beneficiary is a non-metropolitan statistical areas (MSA) or rural area. This add on no longer applies to episodes with end-dates on or after April 1st. The end date is the date of discharge or day 60 if the patient is not discharged.

Advance Beneficiary Notice Quick Reference Guide Now Here!

Now available on our Beneficiary Notices Initiative (BNI) web-page at http://cms.hhs.gov/medicare/bni is a color brochure entitled "What Doctors Need to Know about the Advance Beneficiary Notice (ABN)". The links to the brochure can be found in the ABN (CMS-R-131) segment of the BNI web-page. It is available in two different formats, the first is a four-page 8.5"x11" size and the second is a reduced 5.5"x8.5" size. The brochure includes decision trees for deciding whether or not to give an ABN, in general and in EMTALA situations, as well as a complete list of statutory exclusions from Medicare benefits.

Quality Assessment and Performance Improvement (QAPI) Conditions of Participation for Hospitals

The Centers for Medicare & Medicaid Services (CMS) published a new rule instructing hospitals to develop and implement quality improvement programs in an effort to further reduce medical errors.

Under a final rule announced recently, hospitals must develop and implement a quality assessment and performance improvement (QAPI) program that will identify patient safety issues and reduce medical errors in hospitals.

"This rule will encourage a greater emphasis on patient safety in hospitals," Health and Human Services Secretary Tommy G. Thompson said. "This serves as another step toward bringing improved patient safety, accountability and quality to the forefront of medical practice. Ultimately, we hope to create an environment where hospitals and other providers compete based on the quality of care that they provide to their patients."

To review the rule in its entirety, please click here: http://frwebgate3.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=35484614361+3+0+0&WAISaction=retrieve

Clearing Up the 3-Day Window

Transmittal A-03-013 provides needed clarification to the 3-day payment window. At several hospital open door forums, providers have asked CMS to clarify what services, when provided with three days of an inpatient hospital admission, are subject to bundling under the 3-day payment window. The transmittal, available here: http://cms.hhs.gov/manuals/pm_trans/A03013.pdf, provides detailed instructions to our fiscal intermediaries (FIs) on this topic.



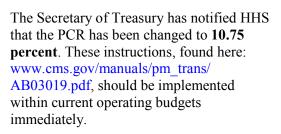
Additionally, Part A services furnished by skilled nursing facilities, home health agencies, and hospices are excluded from the payment window provisions. Further, we revised the regulations at §§ 412.2(c)(5) and 413.40(c)(2) to exclude maintenance renal dialysis services from services that are subject to the payment window.

This instruction also revises the revenue codes for diagnostic services in the Common Working File, §3610.3 of the Medicare Intermediary Manual, and §415.6 of the Hospital Manual.

In addition, CMS also issued instructions clarifying the application of the payment window for PPS and formerly PPS—exempt hospitals. Please click here: www.cms.gov/manuals/pm_trans/A03008.pdf to get details regarding CMS' clarification of this issue, which reads, in short, that long-term care hospitals (LTCHs) and inpatient rehabilitation hospitals (IRFs) are subject to a 1-day payment window; however, they are not subject to the acute care hospital 3-day payment window.

Interest Rate for Over and Underpayments

Medicare Regulation 42 CFR §405.378 provides for the assessment of interest at the higher of the private consumer rate (PCR) or the current value of funds rate (two percent for calendar year 2003).



Clarification of Policy for Billing Injectable Medications

Given time constraints, a statement provided in response to a question concerning billing Medicare for injectible medications at the January 31st End Stage Renal Disease & Clinical Laboratory forum did not thoroughly reflect the agency's position. Here, now, is a more accurate response:

<u>For medications supplied in vials with preservatives or otherwise intended for use in providing multiple doses</u>: In all circumstances, the patient should only be billed for the amount administered to the patient.

<u>For medications supplied in vials labeled for single use</u>: In general, physicians and facilities should bill what they administer to the patient. In the event that the remainder of a vial needs to be discarded, because only one patient needs a portion of the contents in the vial, then the remainder can be discarded. In that situation, the entire contents of the vial can be billed. In no circumstances can multiple patients be billed for the entire contents of a single vial, when the patients each received a portion of the drug from the same vial.

With appropriate procedures, it is now safe to reenter a medication vial labeled as single use. On July 5th, 2002, CMS issued a new procedure, developed with the approval of the Centers for Disease Control, was for safe re-entry into "single use" vials. (A copy of this procedure can be found at www.nraa.org/letters/Tunis_Letter.doc and was discussed on page two of the September 2002 issue of the Open Door Forum Newsletter.) We expect this procedure to be used whenever feasible for efficient use of medications.

Remittance Advice Remark and Reason Code Update

CMS recently issued instructions through Transmittal AB-03-012 updating remark and reason codes for intermediaries, carriers and Durable Medical Equipment Regional Contractors (DMERCs).

CMS is the national maintainer of the remittance advice remark code list that is one of the code lists mentioned in ASC X12 transaction 835 (Health Care Claim Payment/Advice) version 4010 Implementation Guide (IG). Under HIPAA, all payers have to use reason and remark codes approved by X-12 recognized maintainers instead of proprietary codes to explain any adjustment in the payment. As a result, CMS received a significant number of requests for new remark codes and modifications in existing remark codes from non-Medicare entities.

The code changes initiated by Medicare have been identified to single out codes that must be implemented by the contractors and the Shared System maintainers. For further details and to review the full list of remark codes, please click here:

www.cms.gov/manuals/pm trans/AB03012.pdf

Application of Least Costly Alternative to Vitamin D Analogues

Some Medicare contractors have developed Local Medical Review Policies (LMRPs) using least costly alternative (LCA) analysis for the Vitamin D analogues Zemplar, Calcijex, and Hectoral. CMS has asked contractors to suspend further such activity pending our look into questions of whether or not these drugs are equivalent clinical alternatives.

As part of CMS' inquiry, CMS staff reviewed medical evidence and met with multiple stakeholders. In addition, clinical trials are in progress comparing the effects of Zemplar and Calcijex on biochemical markers, morbidity and mortality. CMS soon expects to have enough additional data to indicate whether LCA can be appropriately applied to Vitamin D analogues.

Prior to February 2004 and further notice, contractors are not to implement LCA-based Vitamin D policies. All other uses of LCA analysis and Vitamin D LMRP are not limited.

Single Site Survey for Critical Access Hospitals



On February 13th, 2003, CMS released S&C-03-12, a policy letter to the state survey agencies. Some providers in the Critical Access Hospital (CAH) community requested that CMS make available a coordinated survey approach when conducting surveys of CAHs with multiple providers in their CAH-based rural network. A coordinated survey approach would allow the state agency to survey all the various providers under the CAH umbrella concurrently. This approach would not affect the surveys conducted by approved accrediting organizations.

CMS policy is that we are willing to explore the coordinated survey concept with individual state agencies and looks forward to working with those interested in using this survey approach. To review the PDF file, please click here: www.cms.hhs.gov/medicaid/ltcsp/sc0312.pdf

Great News for Rural Providers!

Along with the recent good news regarding the rural standardized amount, CMS ensured access to care for rural beneficiaries who are served by critical access hospitals (CAHs) in frontier and remote areas and offers relief to the physicians and other providers who staff these hospitals. The rule permits staffing by a registered nurse during temporary periods when a physician or other qualified provider is not available.

The rule, which was published in the December 31st, 2002 Federal Register, will be effective on March 1st. Services provided on or after January 1st and before March 1st will be paid under the 2002 fee schedule. Please see the rule here: http://cms.gov/regulations/pfs/cms1204f2.pdf



President's Budget Continues Initiatives for the Uninsured: Efforts Include Tax Credits and Investments to Expand Access

Secretary Tommy G. Thompson recently announced that the 2004 budget plan includes new initiatives and expands existing programs to improve access to health care and coverage for more than 40 million Americans without health insurance.

"President Bush's budget will give millions more Americans the security of health insurance and improved access to needed health care and preventive services," Secretary Thompson said. "Recognizing that far too many Americans still lack health insurance, we must move forward on many fronts to help low- and moderate-income Americans, especially children, get care and stay healthy."

Key elements of the President's fiscal year 2004 budget plan to help the uninsured can be found here: www.hhs.gov/news/press/2003pres/20030211.html

Also, in recognition of the high priority that President Bush has placed upon the need to improve access to health care and coverage for Americans without health insurance, CMS Chief Operating Officer and Deputy Administrator Ruben King-Shaw Jr. has been appointed to the Treasury Department to work on the development and implementation of the health tax credit passed by Congress as part of the 2002 trade bill. In addition to maintaining responsibilities at CMS, Mr. King-Shaw's six-month appointment to Treasury will be of tremendous help to the many thousands of unemployed workers who will benefit from this temporary relief to purchase health care.

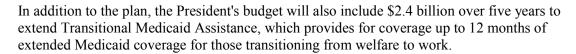
President Bush to Propose Innovative Improvements in States' Health Coverage for Low-Income Americans

HHS Secretary Tommy G. Thompson announced that the President George W. Bush will propose a sweeping new plan to enable states to improve health insurance coverage for low-income Americans through immediate additional funding and an SCHIP-type flexibility.

"The time to modernize Medicaid is here," Secretary Thompson said. "The states' budget crises are threatening the progress we've made in expanding health insurance, and at the same time the old Medicaid rules are a straight-jacket, restraining creative new approaches that could preserve coverage and expand it to more Americans in need."

The plan gives states the upfront investment and flexibility to design health care programs that best meet the needs of their citizens and expand coverage to more people, including the mentally ill, chronically ill, those with HIV/AIDS and those with substance abuse problems.

Secretary Thompson is consulting with governors in developing the new plan, which would be optional for states. For more details on the plan, please click here: www.hhs.gov/news/press/2003pres/20030131d.html





CMS Streamlines and Simplifies Quality and Personnel Rules for Clinical Laboratories

The Centers for Medicare & Medicaid Services recently issued new quality and personnel rules for laboratory services that are designed to enhance patient safety while making it easier for laboratories to understand and comply with these requirements. The changes are part of a broader effort across HHS to restore common sense to the regulatory process and promote higher-quality care.

The rules, which complete the implementation of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), apply to laboratory testing in all settings - including commercial, hospital, and physician office laboratories. The requirements are tailored to the complexity of the testing.

Currently about 176,000 laboratories are certified under CLIA. The new rules will have the greatest impact on the 38,000 labs that are authorized to perform high or moderate complexity testing.

"For the first time, CLIA requirements have been reorganized in a more logical fashion to parallel the flow of a patient specimen through the laboratory," CMS Administrator Tom Scully said. "This reorganization should help laboratories understand and apply the requirements more easily, and reduce laboratory errors."

For further details on the final rule, which has been published in the January 24th *Federal Register*, please click here: http://frwebgate3.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=35484614361+21+0+0&WAISaction=retrieve

Strength in Numbers

Recently, and to strengthen the presence and commitment to policy outreach across the country, CMS Administrator Tom Scully has appointed CMS Regional Administrators (RA) to serve as Co-chairs in all Open Door Forums. "This is a significant step forward in ensuring that Medicare stakeholders from across the country continue to have an opportunity to interact with all of our policy leaders," said Tom Barker, CMS Senior Advisor to the Administrator for Policy and Outreach.



Dr. Randy Farris, the Regional Administrator in Dallas and, now, Physician Open Door Forum Co-Chair said, "Although RAs have been engaged with the Open Door Imitative over the past year and a half, this is

clearly another step to further integrate the Regional Offices' role into the Open Door process."

To see the complete list of RA Co-chairs and the March 2003 schedule, please visit the Open Door web-page at: www.cms.hhs.gov/opendoor



Transmittal B-03-002: Delay in Implementation of New ICD-9 CM codes

http://cms.hhs.gov/manuals/pm trans/B03002.pdf

Transmittal B-03-003: Processing Initial Denials, of the DMEPOS Refund Requirements - Implementation of Limits on Beneficiary Liability for Medical Equipment and Supplies

http://cms.hhs.gov/manuals/pm trans/B03003.pdf

Transmittal AB-03-008: Clarification of Physician Certification Requirements for Medicare Hospice www.cms.gov/manuals/pm trans/AB03008.pdf

Final Minimum Data Set (MDS) User's Manual http://cms.hhs.gov/medicaid/mds20/man-form.asp

On the Road Again!

CMS will be on the road again to host Open Door Forums near you! Currently, the upcoming tour includes the

March 20th Health Plans Open Door Forum in the San Francisco Regional Office and the April 28th Physician Open Door Forum from Powell, Wyoming as special guests of the Wyoming and Montana Medical Societies.

Please see the mail box at the bottom of this page to let us know if you are interested in hosting an Open Door Forum near you.



Special Open Door Forums

In addition to the New Freedom Initiative Open Door Forum announced on page three, CMS is excited to announce that we will host an Open Door Forum specifically designed to discuss the Program of All-Inclusive Care for the Elderly (PACE) on April 15th at 2 PM EST.

PACE is a new capitated benefit for the frail elderly provided by a not-for-profit or public entity that features a comprehensive medical and social service delivery system authorized by the Balanced Budget Act of 1997 (BBA). PACE features a comprehensive service delivery system and capitated Medicare and Medicaid financing and a interdisciplinary team approach in an adult day health center supplemented by in-home and referral service in accordance with participants' needs.

To read details on CMS' efforts with PACE including the PACE Interim Final Rule (published October 1st, 2002), technical information on the regulations and PACE protocol, and to receive information for State Medicaid Agencies, State Administering Agencies, and Providers, please click here: http://cms.hhs.gov/pace/default.asp

The National PACE Association (NPA) is another great resource for information on PACE. For that site, please click here: www.npaonline.org/

For any information regarding the Open Door Forum Initiative, please feel free to contact Tom Barker, Special Assistant to the Administrator for Policy and Outreach at (202) 690-0056 or: tbarker@cms.hhs.gov

